K100252

APR - 9 2010

SONOMED INC.

510(K) Summary

Sonomed, Inc
1979 Marcus Avenue Lake Success, NY 11042, USA
Tel 800-227-1285 / 516-354-0900 Fax 516-354-5902

510(K) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR Part 807.92

Date: January 22, 2010

1. Company and Correspondent making the submission:
   Name: Sonomed Inc.
   Address: 1979 Marcus Ave
   Lake Success, NY, 11798
   U.S.A.
   Telephone: 516-354-0900
   Fax: 516-354
   Website: www.sonomed.com
   Contact: Mr. Charles C. O'Neal, Quality Manager
   E-mail: coneal@escalonmed.com

2. Device:
   Trade/proprietary name: Master-Vu A-scan
   Common Name: Diagnostic ultrasound system
   Classification Name: System, imaging, pulsed echo, ultrasonic

3. Predicate Devices:
   Manufacturer: Sonomed, Inc.
   Device: E-Z Scan 5500+ A-Scan / B-Scan System
   510(k) Number: K040668

4. Classification Names & Citations:
   Classification: Class 2
   Classification Code: 21CFR 892.1560, 1570, IYO, ITX, system, imaging, pulsed echo, ultrasonic,

5. Description:
   The Master-Vu A-Scan is a portable ultrasonic A-scan system intended for use in ophthalmic applications. The system allows for the measurement of several key ocular features including axial length (AXL), anterior chamber depth, and lens thickness while also aiding in the calculation of associated IOL power for implanted lenses.

   The Master-Vu A-Scan system consists of a solid A-probe, a base unit which houses the electronics, a foot pedal switch, and a USB cable which provides a means of interfacing the system with a host computer.

   The standard Master-Vu software allows any Microsoft Windows compatible host computer (PC) to function as the control panel of the system. The host computer is not supplied by Sonomed as part of the Master-Vu A-Scan system and must be provided by the end user. Minimum requirements for compatible host computers are supplied in the documentation accompanying the system.

   The Master-Vu software is compatible with the Microsoft Windows XP or Microsoft Windows Vista operating systems, and uses the features of the Windows graphical user

interface to direct the operation of the system and maintain patient records. Patient data may be analyzed, saved, retrieved, and printed through the computer interface at the operator's discretion. The Microsoft Windows operating system provides an adequate and user-friendly interface for a wide variety of clinical environments.

6. Indications for Use:
   The Master-Vu A-Scan provides intraocular measurements of anterior chamber depth, lens thickness, and axial length which can be used with published industry-accepted refractive formulas to calculate associated IOL powers for implanted lenses.

7. Comparison with predicate device:
   Sonomed, Inc. believes that the technologies incorporated into the Master-Vu A-scan are substantially equivalent to those of the E-Z Scan 5500+ A-scan / B-scan system.

8. Safety, EMC and Performance Data:
   Electrical, mechanical, environments safety and performance testing according to standard IEC 60601-1, IEC 60601-2-37, and EN/IEC 60601-1-2(2001) are currently pending.

9. Conclusions:
   In accordance with the Federal Food, Drug and Cosmetic Act 21 CFR Part 807 and based on the information provided in this premarket notification Sonomed, Inc. concluded that the Master-Vu A-scan is safe and effective and substantially equivalent to predicate devices as described herein.

10. Sonomed Inc. will update and include in this summary any other information deemed reasonably necessary by the FDA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

APR - 9 2010

Charles C. O'Neal
Quality Manager
Sonomed, Inc.
1979 Marcus Avenue, Suite C150
LAKE SUCCESS NY 11042

Re: K100252
Trade/Device Name: Master-Vu A-Scan, Model MV4500
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO
Dated: March 24, 2010
Received: March 25, 2010

Dear Mr. O'Neal:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Master-Vu A-Scan, Model MV4500 as described in your premarket notification:

Transducer Model Number

Model DCT-10 A-Scan Transducer

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Shahram Vaezy at (301) 796-6242.

Sincerely yours,

Donald J. St.Pierre
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure(s)

Indications for Use

510(k) Number (if known): K100252

Device Name: Master-Vu A-Scan

Indications for Use: The Master-Vu A-Scan provides intraocular measurements of anterior chamber depth, lens thickness, and axial length which can be used with published industry-accepted refractive formulas to calculate associated IOL powers for implanted lenses.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety

510(k) Number K100252

Diagnostic Ultrasound Indications For Use Form

510(k) Number K100252
System Model MV4500 Master-Vu A-Scan
Transducer - Not Applicable -

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Tracks 1 & 3)	A	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic	N							
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intraoperative (Specify)								
	Intraoperative (Neurological)								
	Pediatric								
	Small Organ (Specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-Rectal								
	Trans-Vaginal								
	Trans-Urethral								
	Trans-Esophageal (Non-Cardiac)								
	Musculo-Skeletal (Conventional)								
	Musculo-Skeletal (Superficial)								
	Intravascular								
	Other (Specify)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-Esophageal (Cardiac)								
	Intra-Cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral Vessel								
	Other (Specify)								

N = New Indication | P = Previously Cleared by FDA | E = Added Under This Appendix

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K100252

Diagnostic Ultrasound Indications For Use Form

510(k) Number K100252
System - Not Applicable -
Transducer Model DCT-10 A-Scan Transducer

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Tracks 1 & 3)	A	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic	P							
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intraoperative (Specify)								
	Intraoperative (Neurological)								
	Pediatric								
	Small Organ (Specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-Rectal								
	Trans-Vaginal								
	Trans-Urethral								
	Trans-Esophageal (Non-Cardiac)								
	Musculo-Skeletal (Conventional)								
	Musculo-Skeletal (Superficial)								
	Intravascular								
	Other (Specify)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-Esophageal (Cardiac)								
	Intra-Cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral Vessel								
	Other (Specify)								

N = New Indication | P = Previously Cleared by FDA | E = Added Under This Appendix

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Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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